

Application No. 10/634,477

Docket No.: NY-ROCHE 202-US

Amendment dated January 29, 2008

Reply to Office Action of December 12, 2007

**REMARKS**

Entry of the amendment is requested.:

Claims 1, 5-16, 19 and 21-26 will be pending.

Claims 1 and 6 are amended herein and the amendments are discussed *infra*.

The allowance of claim 16 is noted with appreciation.

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph. The Examiner called for establishing a nexus between items (d)-(g) and the recited analog to parallel (a)-(c) of the claim.

Parallel language has been provided for (d), (e) and (f), but not (g), because (g) is a complete molecule, fully described in the specification, and no nexus need be established.

The Examiner has rejected claims 1, 5-15, 19 and 21-26 on provisional double patenting grounds in view of copending application 10/706,701. Applicants have considered this rejection and traverse.

At the start, they question the inclusion of composition claims 13-15 in this rejection, since 10/706,701 does not present any composition claims. Applicants note further that in the second provisional double patenting rejection, in view of 11/013,560, claims 13-15 were not included. Applicants note that 11/013,560 present no composition claims either. Clarification is requested.

Regarding this rejection the Examiner states that the claimed methods have "one step, administering erythropoietin, thus the resulting effect will be the same."

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While applicants will not comment on whether or not they agree with this statement, claim 1 has now been amended to specifically recite that a specific patient pool is the subject of the therapy, *i. e.*, patients who suffer from both non-insulin dependent diabetes and iron distribution disturbances.

The Examiner has pointed to references allegedly showing overlap between the conditions recited in the claims under consideration in the rejection. Overlap, however, is not the same as *de facto* equivalence. In other words, a patient with non-insulin dependent diabetes and iron distribution disturbances does not necessarily suffer from heart disease. It is not obvious that what would function therapeutically for one condition would in fact function for the other. In the absence of such a showing, the rejection is untenable and should be withdrawn.

With respect to the second rejection, *i.e.*, of claims 1, 5-12, 19 and 21-26 in view of 11/013,560 applicants point out that patients suffering from chronic inflammatory intestinal disease are not necessarily suffering from non-insulin dependent diabetes and disturbances in iron distribution. There is no showing that successful treatment of one of these conditions would be expected to be successful for the others.

In view of the foregoing, withdrawal of the rejections, especially as they apply to claims 13-15, and allowance of this application is believed proper, and is urged.

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The Examiner is invited to telephone the undersigned should any issues remain which might be clarified by telephone interview.

Dated: January 29, 2008

Respectfully submitted,

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